

Title: An Emergency Department-Based Study to Reduce Adolescent Pregnancy

Short Title Reducing Adolescent Pregnancy

eIRB Number

Protocol Date: 7 July 2019

Amendment 1 Date: 7/23/19

Amendment 3 Date:

Amendment 2 Date:

Amendment 4 Date:

Study Principal Investigator

Cynthia J. Mollen, MD, MSCE

3501 Civic Center Blvd.
Philadelphia, PA 19104
Phone: 215-590-1944
Email: MollenC@email.chop.edu

TABLE OF CONTENTS

Table of Contents	ii
Abbreviations and Definitions of Terms.....	iv
Abstract	v
Background Information and Rationale	1
1.1 INTRODUCTION.....	1
1.2 NAME AND DESCRIPTION OF INVESTIGATIONAL PRODUCT OR INTERVENTION.....	1
1.3 RELEVANT LITERATURE AND DATA.....	1
1.4 COMPLIANCE STATEMENT.....	2
2 STUDY OBJECTIVES	3
2.1 PRIMARY OBJECTIVE (OR AIM)	3
2.2 SECONDARY OBJECTIVES (OR AIM).....	3
3 INVESTIGATIONAL PLAN	3
3.1 GENERAL SCHEMA OF STUDY DESIGN	3
3.1.1 <i>Advanced Practice Nurse Screening, Consent, and Training</i>	4
3.1.2 <i>Screening Phase</i>	4
3.1.3 <i>Phase 1: Contraceptive Counseling</i>	4
3.1.4 <i>Phase 2: Feedback and Follow-Up</i>	4
3.1.5 <i>Phase 3: Subgroup Interview</i>	5
3.2 STUDY DURATION, ENROLLMENT AND NUMBER OF SITES	5
3.2.1 <i>Duration of Study Participation</i>	5
3.3 TOTAL NUMBER OF STUDY SITES/TOTAL NUMBER OF SUBJECTS PROJECTED.....	5
3.4 STUDY POPULATION.....	5
3.4.1 <i>APP Population</i>	5
3.4.2 <i>Patient Population</i>	6
4 STUDY PROCEDURES.....	6
4.1 SCREENING.....	6
4.2 APP TRAINING	7
4.3 CONTRACEPTIVE COUNSELING.....	7
4.4 FEEDBACK & FOLLOW-UP	8
4.5 SUBGROUP INTERVIEW	8
4.5.1 <i>Theoretical Model to Guide Interviews</i>	8
4.6 SUBJECT COMPLETION/WITHDRAWAL	9
5 STUDY EVALUATIONS AND MEASUREMENTS.....	10
5.1 SCREENING AND MONITORING EVALUATIONS AND MEASUREMENTS	10
5.1.1 <i>Electronic Medical Record Review</i>	10
5.1.2 <i>Confidential Screening Interviewing to Assess Eligibility</i>	10
5.1.3 <i>Contraceptive Counseling</i>	10
5.1.4 <i>Post-Counseling Electronic Medical Record Review (at 8 weeks post-ED visit)</i>	10
5.1.5 <i>Semi-Structured Interviews</i>	10
5.2 SAFETY EVALUATION.....	10
6 STATISTICAL CONSIDERATIONS.....	11
6.1 PRIMARY ENDPOINT.....	11
6.2 STATISTICAL METHODS.....	11
6.2.1 <i>Baseline Data</i>	11
6.2.2 <i>Efficacy Analysis</i>	11
6.2.3 <i>Safety Analysis</i>	13
6.3 SAMPLE SIZE AND POWER	13

7	SAFETY MANAGEMENT	14
7.1	CLINICAL ADVERSE EVENTS	14
7.2	ADVERSE EVENT REPORTING	14
8	STUDY ADMINISTRATION	14
8.1	DATA COLLECTION AND MANAGEMENT	14
8.2	CONFIDENTIALITY	14
8.3	REGULATORY AND ETHICAL CONSIDERATIONS.....	14
8.3.1	<i>Data and Safety Monitoring Plan</i>	<i>14</i>
8.3.2	<i>Risk Assessment.....</i>	<i>16</i>
8.3.3	<i>Potential Benefits of Trial Participation</i>	<i>18</i>
8.3.4	<i>Risk-Benefit Assessment</i>	<i>18</i>
8.4	RECRUITMENT STRATEGY	18
8.5	INFORMED CONSENT/ASSENT AND HIPAA AUTHORIZATION	ERROR! BOOKMARK NOT DEFINED.
8.5.1	<i>Waiver of Parental Consent.....</i>	<i>Error! Bookmark not defined.</i>
8.6	PAYMENT TO SUBJECTS/FAMILIES.....	19
8.6.1	<i>Reimbursement for travel, parking and meals</i>	<i>19</i>
8.6.2	<i>Payments to subject for time, effort and inconvenience (i.e. compensation).....</i>	<i>19</i>
9	PUBLICATION.....	19
10	REFERENCES.....	19

ABBREVIATIONS AND DEFINITIONS OF TERMS

ED	Emergency Department
REDCap	Research Electronic Data Capture
EMR	Electronic Medical Record
APP	Advanced Practice Provider
TPB	Theory of Planned Behavior
eTPB	Ecologically-expanded Theory of Planned Behavior

ABSTRACT

Context:

Unintended adolescent pregnancy is a major public health problem in the United States that results in negative, multi-generational effects on the social, educational and health outcomes of young mothers and their children. Adolescent pregnancies cost an estimated \$9.4 billion each year.^{1,2} Although rates of adolescent pregnancy declined 25% between 2007 and 2011,³ they remain among the highest in the developed world.⁴ Importantly, the decline has largely been due to increased contraceptive use;^{5,6} still, half of adolescent pregnancies are due to *lack* of contraceptive use, with another large portion due to incorrect or inconsistent use.⁵⁻⁹ Efforts to further increase adolescent contraceptive use remain desperately needed. This data will help to elucidate factors that affect decision-making as well as barriers and facilitators to conception initiation in the ED setting, allowing us a critical understanding that will lead to developing patient-centered approaches for increasing contraception initiation among these patients.

Objectives:

Primary Objective: Assess intention to initiate contraception (“high”=very/somewhat likely vs. “low”=unsure/not likely/definitely not on Likert scale survey) among females aged 16 to 18 years who receive ED-based contraceptive counseling.

Secondary Objectives:

1. Among the same population, assess completion of a referral for any contraceptive care, defined as attendance at a referral site within 4 weeks after the index ED visit.
2. Assess the proportion who ultimately initiate contraception through electronic medical record documentation (i.e., visit note, procedure note, medication review) and participant report (follow-up calls).
3. Use qualitative interview methodology to explore attitudes, barriers, and facilitators that affect decisions to 1) express intention to initiate contraception, 2) complete a referral for contraceptive care, and 3) ultimately initiate contraception among this unique group of high-risk adolescents.

Study Design: Prospective Cohort

Setting/Participants:

This study will be conducted in the emergency department at the Children’s Hospital of Philadelphia, PA and in the emergency department at Children’s Mercy Hospital in Kansas City, MO. This will be a multi-site study.

Advanced Practice Providers (APPs) will be consented and trained to administer contraceptive counseling to patients and answer a post-counseling questionnaire. We anticipate consenting and training a maximum of 12 APPs per site.

We anticipate enrolling 300 patients to obtain 270 evaluable subjects. We anticipate conducting in-depth in person or over-the-phone interviews with 50 enrolled subjects per

site. Patients will be eligible for enrollment if they are females aged 16-18 presenting with high risk of pregnancy. High risk of pregnancy is defined as adolescent females who report recent (within the last 6 months) or likely future sexual activity; do not desire pregnancy within the next year; are not using hormonal contraception or an intrauterine device; and are not currently pregnant.

Study Interventions and Measures:

The study intervention is the implementation of Emergency Department-based contraceptive counseling. An APP will provide this confidential, comprehensive, 10-15-minute counseling. The counseling will assess patients' preferences regarding different methods, knowledge about methods, personal motivations, and environmental factors that may influence contraceptive use, such as partner preference.

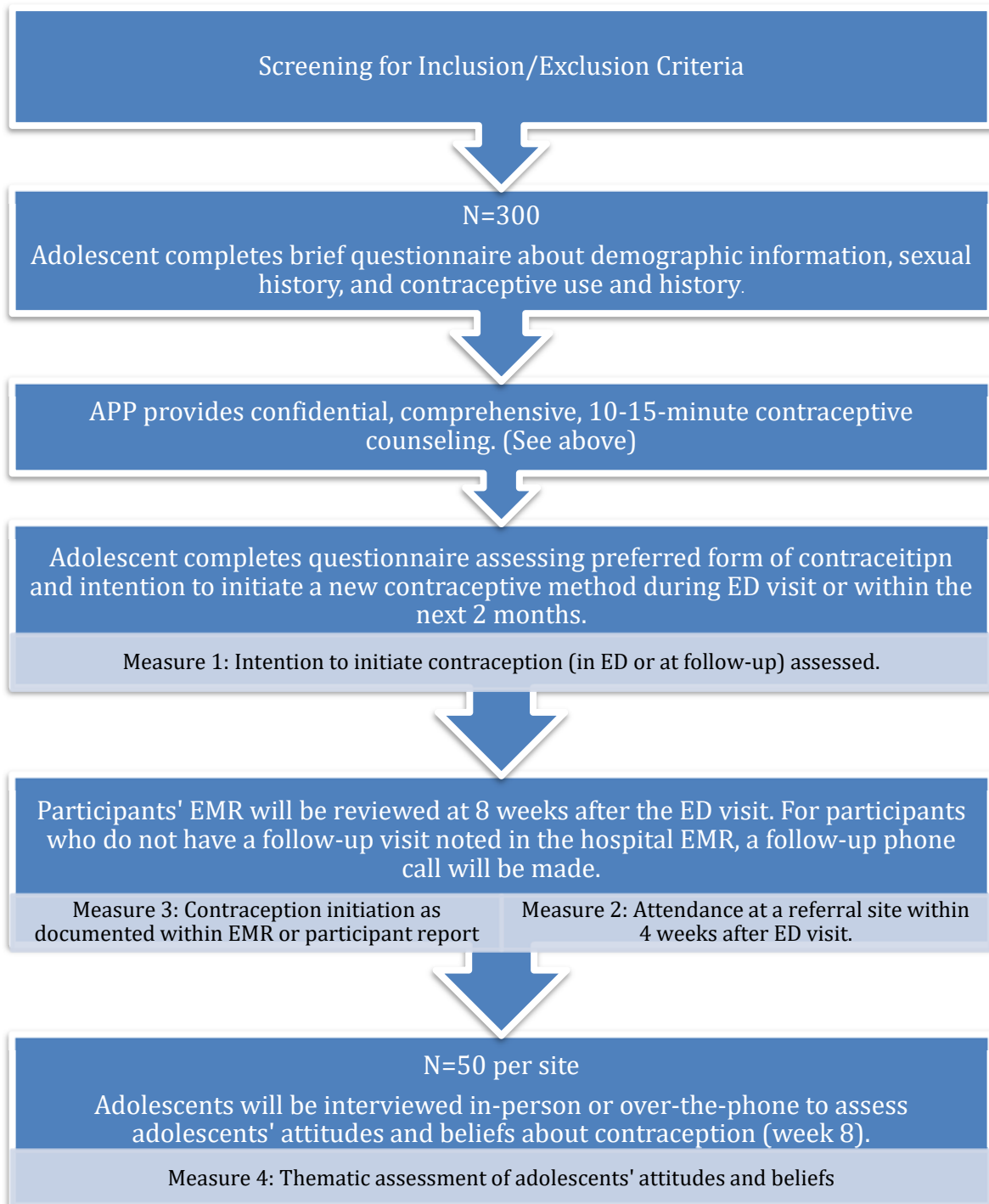
A subgroup of 50 enrolled participants will be interviewed in-person or over the phone, if necessary. All interviews will be conducted by trained members of our research staff and will be audiotaped and professionally transcribed. These interviews will be used as a thematic assessment of adolescents' attitudes and beliefs about contraception.

Table 1 explains the schedule of study procedures.

Figure 1 explains the main study outcome measures as related to each sequenced study procedure.

TABLE 1: SCHEDULE OF STUDY PROCEDURES

Study Phase	Prior to Patient Enrolment	Emergency Department Visit	8 weeks post-ED visit	8-12 weeks post-ED visit
APP Consent and Training	X			
Screening & Eligibility Review		X		
Consent		X		
Patient questionnaire 1		X		
Contraceptive Counseling		X		
Patient questionnaire 2		X		
EMR review		X	X	
Follow-up phone call			X	
Eligibility Review				X
In-person or over-the-phone interview				X

FIGURE 1: Schedule of study procedures with outcome measures

BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Unintended adolescent pregnancy rates remain unacceptably high in the United States, and result in poor health outcomes for the young mothers and their babies, as well as significant social and financial costs to communities and society as a whole. While many factors contribute to the high rate of unintended pregnancies in this age group, an important issue that is potentially amenable to intervention is non-use of contraception. Therefore, research focused on increasing initiation of contraception among adolescents, particularly those at high risk of pregnancy, is crucial. One approach that has been understudied is reaching these adolescents in non-traditional sites of clinical care – care settings that do not currently routinely provide contraception services. The Emergency Department (ED) is a setting that is well-positioned to provide these services, as almost 19 million adolescents seek care in EDs each year, and many adolescents are amenable to receiving reproductive health care services in this setting. For the highest-risk patients, the ED is often their only or primary contact with the health care system, and so in this setting we have a vital window of opportunity to improve contraception access for adolescents who are unlikely to be reached through other clinical settings. We seek to capitalize on our prior work and our ED programs focused on sexual health education in order to better understand the decision-making around contraception initiation of adolescents at high risk for pregnancy. Our long-term goal is to reduce unintended pregnancy by improving access to contraception among adolescents seeking care in the ED setting. By elucidating factors that affect decision-making as well as barriers and facilitators to conception initiation in the ED setting, we will gain a critical understanding that will lead to developing patient-centered approaches for increasing contraception initiation among these patients.

1.2 Name and Description of Investigational Product or Intervention

An Emergency Department-Based Study to Reduce Adolescent Pregnancy is a multi-site, mixed methodology study to assess attitudes, barriers and facilitators to initiating contraception in the ED among this high-risk group of patients. We will adapt contraceptive counseling approaches used in outpatient clinical settings to deliver counseling during the ED visit, and our methods will allow us to explore factors associated with initiation of contraception during and after the ED visit as well as issues affecting follow-up after ED care. Ultimately, we will develop a toolkit supporting contraceptive counseling and delivery in the ED, and design processes to support increased use of contraception among adolescents.

1.3 Relevant Literature and Data

Unintended adolescent pregnancy is a major public health problem in the United States that results in negative, multi-generational effects on the social, educational and health outcomes of young mothers and their children. Adolescent pregnancies cost an estimated \$9.4 billion each year.^{1,2} Although rates of adolescent pregnancy declined 25% between 2007 and 2011,³ they remain among the highest in the developed world.⁴ Importantly, the decline has largely been due to increased contraceptive use;^{5,6} still, half of adolescent pregnancies are due to

lack of contraceptive use, with another large portion due to incorrect or inconsistent use.⁵⁻⁹ Efforts to further increase adolescent contraceptive use remain desperately needed.

One approach to increase contraceptive use among the highest-risk adolescents is to utilize non-traditional settings, such as the Emergency Department (ED). Adolescents account for almost 19 million ED visits annually, and adolescents in the ED frequently report recent unprotected intercourse, placing them at risk for unintended pregnancy.¹⁰⁻¹⁴ Furthermore, there is growing support for providing sexual and reproductive health services in the ED,¹⁵⁻¹⁹ with several research teams, including our own, having explored various approaches for providing these services.²⁰⁻³⁵ In the ED, we have a vital window of opportunity to improve contraception access for adolescents who are unlikely to be reached through other clinical settings.

Several studies have investigated feasibility and acceptability of providing ED-based sexual health services. These have been primarily single-center studies investigating adolescent preferences for theoretical, not actual, services.^{21-23, 26, 28, 30} Studies of direct service provision have been limited by small sample sizes, or used research processes or research staff, rather than those that can be sustained long-term. Furthermore, the majority of studies have focused on screening for sexually transmitted infections (STIs),^{36,29,33,34,36,37} rather than pregnancy prevention, with the latter focused on emergency contraception.^{22,34,38} An important gap remains in understanding how to optimally deliver contraceptive counseling services in the ED that maximize contraceptive uptake. Important questions remain unanswered, such as which contraceptive services (counseling, prescribing, or placement of medium and long-acting reversible contraceptives), should be offered in the ED, and which should be provided through referral to sites with contraceptive specialists. Recognizing that a “one size fits all” model is unlikely to be successful, we must identify patient-centered factors that impact preferences to understand what drives decision-making around contraceptive initiation for adolescents in the ED. Understanding adolescent decision-making will allow us to utilize the most effective processes for the ED setting, and to make optimal use of resources, while maximizing the likelihood of adolescent contraceptive initiation. The goal of this application is to examine whether adolescents who receive structured contraceptive counseling in the ED have a stronger preference for initiating a method in the ED or prefer to be referred. We will use a theoretical framework to explore domains that likely predict these preferences. In addition, we will assess rates of contraception initiation after the ED visit.

This proposal addresses a major gap in health care access for this vulnerable population and is consistent with Healthy People 2020 objectives: “Reducing pregnancies among adolescent females (FP-8)” and “Increasing the proportion of sexually active persons aged 15 to 19 years who use hormonal or intrauterine contraception to prevent pregnancy (FP-11).”³⁹ In addition, the proposal directly addresses one of the high-priority research areas of the Population Dynamics Branch of NICHD: “Behavioral research on the use and non-use of contraception.”⁴⁰

1.4 Compliance Statement

This study will be conducted in full accordance all applicable Children’s Hospital of Philadelphia and Children’s Mercy Hospital Research Policies and Procedures and all

applicable Federal and state laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent, and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

The purpose of this study is to elucidate factors that impact preferences around same-day contraception initiation as well as follow-through after referrals for contraception care among adolescents in the ED. The central hypothesis of this research plan is that our work will illuminate specific and unique factors that influence adolescent decisions regarding contraceptive initiation after a counseling session that will subsequently inform future models for patient-centered service provision. We will utilize survey methods (Aims 1, 2 and 3) and in-depth interviews (Aim 4) to achieve our goal.

2.1 Primary Objective (or Aim)

The primary object of this study is to assess intention to initiate contraception among adolescent women ages 16 to 18 years who have received ED-based contraceptive counseling.

2.2 Secondary Objectives (or Aim)

The secondary objectives are to:

- Assess completion of a referral for any contraceptive care
- Assess proportion who ultimately initiate contraception
- Explore attitudes, barriers, and facilitators that affect adolescent women's decision to 1) express intention to initiate contraception, 2) complete a referral for contraceptive services, and 3) actually initiate contraception.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This is a prospective cohort study of female patients ages 16-18 years old presenting to the Emergency Department at the Children's Hospital of Philadelphia and Children's Mercy Hospital. Prior to screening and enrolling any patients, a maximum of 12 Advanced Practice Providers per site will be approached, consented, and trained in contraceptive counseling. During enrollment in the ED and after patients are screened to determine eligibility, a trained APP will conduct confidential contraceptive counseling during the ED visit. Following this counseling, both the patient and APP will complete a questionnaire to provide feedback on the counseling session. At 8 weeks post-ED visit, the study team will conduct an EMR review or follow-up phone calls to assess patient initiation of a contraceptive method and completion of follow-up visits. A total of 300 patients across both

sites will be enrolled in the study. Of these 300 patients, 50 patients per site will be invited to complete an in-depth interview assessing factors that influenced patient follow-up and/or initiation of contraception post-contraceptive counseling.

The proposed study will elucidate factors that affect adolescents' decisions to initiate contraception in the ED, and to follow-through with referrals for contraception services, after receiving standardized contraception counseling. This project is the next step in our ongoing line of research to improve sexual and reproductive health services in the ED. We will build upon existing ED programs focused on sexual health education and evaluate, in-depth, factors contributing to individual decision-making. This project will move us towards our long-term goal: reducing unintended pregnancy by improving access to contraception among high-risk teens.

3.1.1 Advanced Practice Nurse Screening, Consent, and Training

APPs working in the Emergency Department for at least 6 months will be approached to determine interest in participation in this study. Those who are interested will provide written consent and subsequently be trained to use patient-centered, semi-structured clinical interview techniques, consisting of two 4-hour training sessions.

3.1.2 Screening Phase

Potentially-eligible patients will be identified by APP subjects during the course of normal clinical care, if the APP subject is part of the patient's care team. If a patient is eligible based on information from clinical care, the APP subject will contact a research assistant. Research assistants will verify with the clinical team that patients meet all eligibility criteria and whether the patient has the capacity to consent for themselves. If a patient meets all inclusion / exclusion criteria, written consent / HIPAA authorization will be obtained. Subjects who are 18 years old will provide written consent and HIPAA authorization for their own participation. Subjects who are 16 or 17 years old who are seen in the ED without a parent/legal guardian will provide written consent and HIPAA authorization for their own participation. Subjects who are 16 or 17 years old who are seen in the ED with a parent/legal guardian may elect to have their parent/legal guardian involved in the consent process if desired. In this scenario, subjects will provide assent and permission and HIPAA authorization will be obtained from the parent/legal guardian that is present.

3.1.3 Phase 1: Contraceptive Counseling

Prior to counseling, patients will complete a brief questionnaire to ascertain demographic information, sexual history, and contraception use and history. Afterwards, a trained APP will provide a confidential, comprehensive counseling session lasting 10-15 minutes. This counseling session will include a semi-structured interview regarding contraceptive choice, a review of contraceptive options, an assessment of patient preference and understanding of contraceptive use, and a short client satisfaction survey.

3.1.4 Phase 2: Feedback and Follow-Up

After counseling, patients will complete a questionnaire about their preferred form of contraception and intention to initiate a contraceptive method. They will also complete an adapted Contraceptive Knowledge Assessment and a short questionnaire about their

experience receiving counseling. The APP who provided counseling will also complete a brief follow-up questionnaire regarding the counseling session. Those patients who are interested will receive short-acting, reversible contraception or a contraceptive prescription before the completion of the ED visit. As part of counseling, all participants will be referred to an adolescent gynecologist, a hospital-affiliated adolescent clinic or to a local Title X funded clinic (based on patient preference and access) for additional counseling and to initiate or follow-up on initiation, as applicable. All participants will have a “warm transfer” for follow-up.

At 8 weeks post-ED visit, participants’ EMR will be reviewed to assess referral completion and contraception initiation. If no follow-up visit is noted in the EMR, a follow-up phone call will be made.

3.1.5 Phase 3: Subgroup Interview

A subgroup of 50 participants per site will be invited to complete an in-depth interview in-person or, if necessary, over the phone; this interview, informed by the Ecologically-expanded Theory of Planned Behavior (eTPB) will help assess the factors that supported the decision to start new contraception and/or follow-through to initiate or change contraception. All interviews will be audiotaped and professionally transcribed.

3.2 Study Duration, Enrollment and Number of Sites

3.2.1 Duration of Study Participation

The total duration of study participation per subject will be up to 12 weeks. Emergency Department- specific procedures will total 30 minutes, including screening, contraceptive counseling, and counseling feedback, with 10-15 minutes of this time devoted to the contraceptive counseling. Participants’ EMR will be reviewed 8 weeks after the ED visit, and a subset of participants will be interviewed in-person or over the phone within 4 weeks following the EMR review.

3.3 Total Number of Study Sites/Total Number of Subjects Projected

The study will be conducted at 2 investigative sites in the United States, the Children’s Hospital of Philadelphia and Children’s Mercy Hospital in Kansas City, MO. It is expected that a maximum of 12 APPs per site will be consented and trained to administer the contraceptive counseling.

Recruitment will stop when approximately 270 evaluable subjects are enrolled. It is expected that approximately 300 subjects will be enrolled to produce 270 evaluable subjects, with half at each site.

3.4 Study Population

3.4.1 APP Population

3.4.1.1 Inclusion Criteria

1. Work in the Emergency Department
-

2. Have at least 6 months of experience working in the Emergency Department as an APP
3. Are interested in participating in study procedures

3.4.1.2 Exclusion Criteria

1. There are no exclusion criteria for this population.

3.4.2 Patient Population

3.4.2.1 Inclusion Criteria

1. Females aged 16-18 years who are at high-risk of pregnancy, defined as sexual activity within the last 6 months or likely future sexual activity, defined as within the next 3 months.
2. Females who do not desire to become pregnant within the next year
3. Eligible individuals must be proficient in speaking and reading in English
4. Consent of the adolescent

3.4.2.2 Exclusion Criteria

1. Females who are currently using hormonal contraception or an intrauterine device
2. Females who are pregnant
3. Patient has a developmental delay limiting participation
4. Patients is presenting in the ED after sexual assault
5. Patient is too ill to be screened

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Screening

Potentially-eligible patients will be identified by APP subjects during the course of normal clinical care, if the APP subject is part of the patient's care team. Females ages 16-18 years old (inclusive) who present at the Emergency Department with any chief complaint, will be eligible. Adolescents will be excluded if they are too ill to be screened; have developmental delay limiting participation; present after sexual assault; or are pregnant, as per a pregnancy test conducted as part of standard clinical care. Through standard clinical care, APP subjects will also be able to determine those patients who are at high risk for pregnancy, defined as those who: report recent (within last 6 months) or likely future sexual activity, defined as sexual activity in the next 3 months; do not desire pregnancy within the next year; are not using hormonal contraception or an intrauterine device; and are not currently pregnant.³⁸ After identifying a potentially eligible subject based on these criteria, APP subjects will contact Emergency Department Research Assistants (RA). Research assistants will verify with the clinical team that patients meet all eligibility criteria and whether the patient has the capacity to consent for themselves. Both study sites are staffed with RAs 16

hours/day who are trained to monitor the ED electronic track board for potential research subjects for ED-based studies. If a patient meets all inclusion / exclusion criteria, written consent / HIPAA authorization will be obtained. Subjects who are 18 years old will provide written consent and HIPAA authorization for their own participation. Subjects who are 16 or 17 years old who are seen in the ED without a parent/legal guardian will provide written consent and HIPAA authorization for their own participation. Subjects who are 16 or 17 years old who are seen in the ED with a parent/legal guardian may elect to have their parent/legal guardian involved in the consent process if desired. In this scenario, subjects will provide assent and permission and HIPAA authorization will be obtained from the parent/legal guardian that is present. The consent for the study will encompass the contraceptive counseling with an option for completion of the subgroup interview.

4.2 APP Training

Experts in gynecological health and adolescent health will train the APPs to employ a patient-centered approach that includes a semi-structured clinical interview to determine factors that influence contraceptive choice,^{42,43} followed by a review of contraceptive options and their risks, benefits and side effects. APPs will be trained in approaches rooted in motivational interviewing (MI) to support adolescent autonomy. Use of communication strategies based on open-ended questions and reflective listening greatly enhances the focus on patient preference and autonomy, assisting young women with selecting the method that works best for her.⁴⁴ The training will consist two 4-hour training sessions, the first via webinar, and the second via an in-person interactive session to learn about contraceptive methods and interviewing techniques, and to address common questions. As part of training, APPs will perform counseling with mock patients, and be observed by experts in gynecological health and adolescent health, who will also provide timely feedback after the first counseling session performed by each APP. These experts will use a standardized contraceptive counseling assessment form (based on the methods utilized in the CHOICE project⁴⁵ to rate the APP's performance during each session and provide feedback, and subjects will complete a closed-ended survey assessing fidelity to counseling topics and principles using a Likert scale (1 [strongly disagree] to 5 [strongly agree]).⁵ Details around the surveys are in the Appendix.

4.3 Contraceptive Counseling

After screening and consent procedures are complete, adolescents will complete a brief questionnaire to ascertain demographic information, sexual history, and contraception use and history (based on the NSFG).⁴¹ Next, a trained APP (working a regularly-scheduled ED shift) will provide confidential, comprehensive contraceptive counseling. The counseling session will assess patients' preferences regarding different methods, knowledge about methods, personal motivations, and environmental factors that may influence contraceptive use, such as partner preference.

Counseling will last 10-15 minutes, a duration that is easily integrated into most ED visits, as the average length of stay is 249 minutes (CHOP) and 159 minutes (CMH).

4.4 Feedback & Follow-Up

After counseling, adolescents will complete a questionnaire assessing preferred form of contraception and will be asked their intention to initiate a new contraceptive method during the ED visit or within the next 2 months, using a 5-point Likert-type scale (“very likely” to “definitely not”). Participants will be grouped as “high-intention” to initiate contraception (very or somewhat likely) or “low intention” (unsure, not likely or definitely not) for Aims 1 and 4. Participants will be asked reasons for contraception intention and complete an adapted Contraceptive Knowledge Assessment (CKA).⁴⁶ Study participants will also complete a short questionnaire about their experience receiving counseling loosely based on the Oregon sexual and reproductive health client satisfaction survey⁴⁷ to assess acceptability of the counseling. These surveys will be reviewed as the study progresses in order to make necessary adjustments. Participants will receive a \$20 gift card for participation. As part of standard clinical care, those who are interested in starting a short acting reversible contraception during the visit (e.g., oral pills, patch, vaginal ring, or hormonal shot) will receive medication and/or a prescription before completion of the ED visit. APPs will also complete a brief questionnaire.

As part of counseling, all participants will be referred to an adolescent gynecologist, a hospital-affiliated adolescent clinic or to a local Title X funded clinic (based on patient preference and access) for additional counseling and to initiate or follow-up on initiation, as applicable. All participants will have a “warm transfer” for follow-up. The APP will share clinic information and contact the receiving site via an electronic medical record (EMR) message or phone call. Study staff will assist as needed with making appointments, and will call/text appointment reminders 3 days prior, 1 day prior, and on the day of the appointment. We seek to limit logistical barriers to follow-up care as much as possible.

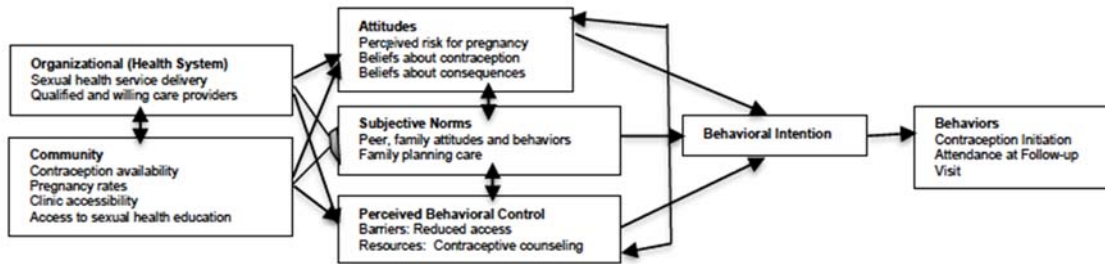
4.5 Subgroup Interview

We will include a subgroup of the 50 enrolled participants per site, as follows: 6-12 participants in each of four groups per site: 1) high intention / completed follow-up and initiated contraception; 2) high intention and completed follow-up but did not initiate contraception; 3) high intention but no follow-up or initiation; 4) low intention. Participants will be interviewed until thematic saturation is reached (i.e. no new themes emerge); we anticipate no more than 50 interviews per site, based on prior experience and literature review of qualitative methods studies.^{48,49} Participants will receive a \$20 gift card for completing the interview. Whenever possible, the in-depth interviews will take place in-person, at a mutually convenient time and in a location easily accessible for the participant. If an in-person interview is not feasible, the interview will be completed by phone. All interviews will be conducted by trained members of our research staff and will be audiotaped and professionally transcribed, and all interviews will be informed by the Ecologically-Expanded Theory of Planned Behavior (eTPB) as described below.

4.5.1 Theoretical Model to Guide Interviews

The Theory of Planned Behavior (TPB) has been used extensively in behavioral interventions with adolescents and sexual health.⁵⁰⁻⁵⁴ However, there is growing support for a broader, ecological perspective to amplify and extend efficacy of sexual risk reduction

interventions.^{55,56} Thus, we will use an over-arching **Ecologically-expanded Theory of Planned Behavior (eTPB)** to inform our interview guide.(see below) The guide will include questions around each of the constructs of the eTPB in order to help us identify factors that supported the decision to start any new contraception in the ED and/or follow-through to initiate or change contraception. In addition, although self-efficacy is not a specific domain in the eTPB, we will assess this construct through questions in the Perceived Behavioral Control (PBC) domain, as well as additional questions drawn the Contraceptive Self-Efficacy Scale.⁵⁷ Sample questions are included in the Appendix.



4.6 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

5.1.1 Electronic Medical Record Review

- Date of birth
- Sex

5.1.2 Confidential Screening Interviewing to Assess Eligibility

- Level of risk for pregnancy, defined as those who: report recently (within the last 6 months) or likely future sexual activity (within the next 3 months); do not desire pregnancy within the next year; are not using hormonal contraception or an intrauterine device; and are not currently pregnant.
- Currently pregnant
- Illness limiting ability to be screened
- Developmental delay limiting patient's participation
- Presenting after sexual assault

5.1.3 Contraceptive Counseling

Adolescents enrolled in the study will complete a questionnaire prior to their contraceptive counseling, to determine participant characteristics, and contraception use and history. After the counseling session, participants will complete an additional questionnaire meant to assess their preferred form of contraception and their intent to initiate contraception, as well as an assessment of the APP's fidelity to the counseling session principles. Participants will be asked reasons for contraception intention and complete an adapted Contraceptive Knowledge Assessment (CKA).⁴⁶ Study participants will also complete a short questionnaire about their experience receiving counseling to assess acceptability of the counseling. The APP's who lead the sessions will also complete a standardized survey.

5.1.4 Post-Counseling Electronic Medical Record Review (at 8 weeks post-ED visit)

- Referral completion
- Contraception initiation

5.1.5 Semi-Structured Interviews

A subset of participants enrolled in Aim 1 will be grouped into four groups of 6-12 participants and take part in semi-structured, in-person interviews conducted by trained interviewers, utilizing the Ecologically-expanded Theory of Planned Behavior (eTPB) described in the Research Strategy. All interviews will be recorded, and data obtained during the interviews will be professionally transcribed and coded for analysis by Dr. Mollen and the study team.

5.2 Safety Evaluation

Subject safety will be monitored by tracking of adverse events by research staff.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

The primary endpoint will be the reported intention to initiate contraception at ED or follow-up visit from survey responses.

Secondary endpoints will include the following:

- The completion of a referral for any contraceptive care as assessed through EMR review or follow-up phone calls
- The initiation of contraception as assessed through EMR review or follow-up phone calls
- Saturation of themes from qualitative interviews that have been coded and analyzed

6.2 Statistical Methods

6.2.1 Baseline Data

Baseline and demographic characteristics will be summarized by standard descriptive summaries (e.g. means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender).

6.2.2 Efficacy Analysis

Proportion who indicate high intention to initiate contraception at ED or follow-up visit will be calculated along with 2-sided 95% CIs. Participant characteristics, factors contributing to initiation (from survey responses), and contraceptive knowledge scores will be compared between “high” and “low” intention groups using chi-square or Fisher’s exact tests for categorical variables and t-test or Wilcoxon rank-sum test for continuous variables. We will use bivariate analyses to evaluate for potential confounders to determine which are retained for final models. Using univariate logistic regression models, we will assess relationships of participants’ characteristics, factors contributing to intention and contraceptive knowledge with the main outcome (intention to initiate contraception, yes/no). Multivariate logistic regression models will be constructed to identify independent predictors of the binary outcome. Clinically important variables will be considered in the multivariate models regardless of achieving statistical significance in the univariate models. Variables significant in the univariate models ($P\text{-value} \leq .20$) and study site (CHOP versus CMH) will be adjusted for covariates in multivariate models. If some variables in the multivariable models may result in multi-collinearity, we will use path analysis to identify correlations between the predictor variables and outcome and to determine direct and indirect relationships of the variables. The path analysis permits the partitioning of the correlation between the variables into direct (i.e., direct effect of a predictor on the outcome) and indirect (i.e., indirect effect of a predictor on the outcome through another predictor variable) effects and measures the relative importance of the causal factors. Potential interaction effects will be examined and included in logistic regression models if significant. The effects of the factors on the outcome may differ by study site. We will assess the differences in the effects of the factors

on the outcome between the two study sites by including interaction effects of study site with the factors in these models.

For data analysis, every attempt will be made to ensure that the extent of missing data is kept at a minimum during the study. Initially we will assess the extent and pattern of missing data using frequencies and cross-tabulations. If data are missing for only a few cases (5% or less), then data analysis will be conducted only on study participants with complete data. However, when such a strategy would result in loss of data from a substantial proportion of participants or would lead to biased or inaccurate results, then sensitivity analysis or some form of imputation will be performed. The form of imputation used will depend on the nature of the data that are missing. If data are missing for primary endpoint (intention to initiate contraception, yes/no), frequencies for missing data by site, patient characteristics, factors contributing to initiation, and contraceptive knowledge scores will be examined. If there are significant associations of missing-ness with any of these characteristics, we would consider imputation methods such as regression technique, hot-deck, or best/worst case (for binary outcomes) and choose the one which would be most appropriate for the type of missing data pattern (i.e. missing at random). If there is partial follow-up, that partial data might inform selection of imputation method. The imputation will be employed if there is a clear evidence of bias due to missing data. Sensitivity analyses will be performed to assess how sensitive results are to reasonable changes in the assumptions that are made for missing data.

Transcripts of interviews will be imported into NVIVO11 (QSR International, Melbourne, Australia) to facilitate coding and analysis, and will be systematically coded as available by the study team. Data analysis will use a modified grounded theory approach. These methods consist of systematic inductive guidelines for collecting and analyzing information to build a theoretical framework for understanding the interview data. An initial coding tree will be developed a priori, based on interview content and the eTPB constructs. Dr. Mollen will train 2 team members per site to code the data. For training, each coder will apply codes independently to 2 transcripts. Dr. Mollen will code the same 2 transcripts, serving as the criterion (or reference) coder to ensure that a high degree of reliability is established. Inter-rater reliability of coding will be assessed using NVIVO software. Discrepancies will be resolved via consensus, with Dr. Mollen serving as the final arbitrator, and the coding tree will be adjusted as needed. Transcripts will be re-coded if significant changes to the coding tree are made; this iterative process will continue until the tree is finalized. The coding tree will be developed into a codebook, with definitions, rules, and examples for each code. Each subsequent transcript will be double-coded, and the team will meet weekly to discuss any discrepancies that arise.

We will use a modified ground theory approach to identify emergent themes within and across the interviews. After coding, relevant portion of coded text will be re-read to identify themes related to each of the eTPB domains, reflecting factors influencing contraceptive initiation, as well as to identify additional themes that are outside of the model. This approach recognizes that additional domains may emerge from analysis besides those already delineated. Moreover, we acknowledge that additional subthemes within each domain may emerge. We will explore whether themes differ among young women by various characteristics (e.g., high/low intention, demographics, completion of follow-up).

6.2.3 Safety Analysis

All subjects entered into the study at Visit 1 will be included in the safety analysis. Frequencies of AEs will be summarized, and SAEs (if any) will be described in detail.

6.3 Sample Size and Power

As this is an exploratory study, we based our sample size on several potential prevalence estimates of “high intention” to obtain contraception as the primary outcome for Aim 1. We assumed a prevalence of 50% high intention and repeated the calculation if the prevalence was only 20%, and calculated the 95% CI around the point estimate. We anticipate similar levels of precision for our other outcomes.

Attrition (%)	Sample size	Prevalence (%)	95% CI
0	300	50	44.3 - 55.7
0	300	20	15.5 - 24.5
10	270	50	44.0 - 56.0
10	270	20	15.2 - 24.8
20	240	50	43.7 - 56.3
20	240	20	14.9 - 25.1
30	210	50	43.2 - 56.8
30	210	20	14.6 - 25.4

Both study sites care for a large number of adolescent females in the study age range (>4600 CHOP and > 2200 CMH, annually), and each of the trained APPs works 13 to 15 8-hour shifts per month. Thus, we anticipate reaching our sample size within 6 months (conservatively estimating each APP will enroll one participant every 4 shifts, accounting for exclusion criteria and refusals).

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

7.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

8 STUDY ADMINISTRATION

8.1 Data Collection and Management

Data will be collected on a study tablet, where it will be immediately entered into a password- and firewall-protected online database, the Research Electronic Data Capture (REDCap, © Vanderbilt University), by a participants using a study tablet, and by a study team member. Each patient will be assigned a unique study ID. Patient identifiers (date of birth and date of visit) will be coded for creation of the analytic dataset. There will be a password protected electronic master list linking the unique study IDs to individuals which will be kept in REDCap, in a secure and separate folder from all other study data. An electronic copy of the password-protected master list will be copied to the office computer of the site study investigator for a length of time post-study as specified by their institution. At CHOP, the electronic copy of the site's password-protected master list will be maintained on the lead study investigator's computer for a minimum of 6 years after study closure completed in accordance with CHOP policy A-3-9.

8.2 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy. The investigator will not use such data and records for any purpose other than conducting the study.

No identifiable data will be used for future study without first obtaining IRB approval or a determination of exemption. The investigator will obtain a data use agreement between provider (the PI) and any recipient researchers (including others at CHOP) before sharing a limited dataset (dates and zip codes).

8.3 Regulatory and Ethical Considerations

8.3.1 Data and Safety Monitoring Plan

Data and safety will be monitored on multiple levels. Dr. Mollen (PI), the lead Research Coordinator and research staff will meet at least weekly to review study progress, safety

issues, recruitment progress, and data quality. The entire research team at both sites will meet monthly (via phone) to review study progress. The Research Coordinator will produce quarterly reports describing recruitment milestones, adverse events, and data quality. We will report any adverse events as directed by the institutional IRB and adverse event (AE) reporting policies. Events will be reported promptly to the PI and the lead Research Coordinator who will make provisions to respond appropriately, ensuring referral to medical/professional resources, as needed.

8.3.1.1 Breach of Confidentiality:

The lead Research Coordinator, along with the PI will ensure that all members of the study team have completed all mandatory confidentiality statements and research ethics trainings, and that data have been handled and stored properly. Annually, research staff will be required to sign a statement acknowledging their receipt and understanding of the confidentiality requirements and pledging to maintain confidentiality of the data to which they have access. If a breach of confidentiality is identified, the PI will immediately notify the IRB by submitting a reportable event. The PI will, as necessary, review and identify how the breach occurred and determine steps to prevent future problems with ensuring participant confidentiality.

8.3.1.2 Continuous Quality Assurance and Quality Control Procedures (QA/QC):

QA/QC will be implemented to ensure compliance with study requirements in areas including recruitment and data collection. Quality control activities will be performed regularly on all Case Report Forms (CRF), electronic data, and participant files to ensure that all data collected is complete and accurate. These will include the reconciliation of data forms, verification of codes and labels, and careful review of each individual data field for omission and errors. This will be the responsibility of the lead Research Coordinator and PI to periodically perform secondary review of these data as an additional QA procedure. When necessary, Good Clinical Practice (GCP) documentation procedures will be followed to amend the data. Any queries generated will be logged, with notification to all applicable parties of the issue and resolution. Problems with data capture stemming from user or design errors will be addressed, as appropriate, with supplemental training for staff, additional instruction for participants, and/or the improvement of problematic entries or procedures. In addition, internal reporting will be maintained to manage visit completion metrics. This reporting system will be utilized by staff members for real-time scheduling of events, checking participant status, determining event completion rates, tracking participants, and collating logistical information crucial for participant retention.

8.3.1.3 Unexpected Adverse Events:

These are defined as any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either: (1) the known or foreseeable risk of adverse event associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or (2) the expected natural progression of any underlying

disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

8.3.1.4 Expected Adverse Event:

This is defined as any event not meeting the definition of unexpected adverse event.

8.3.1.5 Adverse Event Related to Participation:

This is defined as an event that is at least partially caused by participation in the research study. Relatedness is assessed using the following terms: definitely related, probably related, possibly related, unlikely to be related, or unrelated. In general, events that are determined to be at least partially caused by the procedures involved in the research would be considered related to participation in the research. Events determined to be solely caused by an underlying disease, disorder, or condition of the subject, or other circumstances would be considered unrelated to participation in the research.

8.3.1.6 Unanticipated Problem:

This is defined as an incident, experience, or outcome that meets all of the following criteria: (1) unexpected (in terms of nature, severity, or frequency) given: (a) the research procedures that are described in the protocol-related documents, such as the IRB approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; (2) at least possibly related to a subject's participation in the research; and (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.3.1.7 Unanticipated Problem Involving Risks to Subjects or Others:

This is defined as an event that is unexpected, related to the research, and suggests that subjects are at greater risk than was previously known or recognized.

8.3.1.8 Data Safety Monitoring Board

We will convene a Data Safety Monitoring Board comprised of experts in adolescent reproductive health that are not connected to this project or our Institutions. The Board will meet quarterly to monitor participant safety and assess study progress, and will be available to meet on an ad hoc basis if an immediate safety concern arises.

8.3.2 Risk Assessment

Risks to participants are anticipated to be minimal. ED patients with severe illness or who experienced sexual assault will be excluded from this study to minimize the physical and emotional harm to study participants. Counseling sessions will be administered by trained APPs in a confidential setting to avoid emotional discomfort to participants when discussing sensitive matters. There is minor risk of variance of counseling content, but this will be avoided by extensive training that will be provided to the APPs by an adolescent family planning expert at each site. Counseling sessions will be continuously reviewed for quality. Additionally, there is minor risk of unauthorized disclosure of confidential information, which will be made known to participants and will be minimized by the research team's efforts to ensure confidentiality. Every effort will be made to keep data coded. All

recruitment materials (e.g., signed consent forms) and information linking unique identification numbers to participant names will be stored in password-protected electronic files within REDCap. Only Dr. Mollen and designated study staff will have access to these files. Risks are greatly reduced by using secure files, storing data on secure computers, and coding of data. Patients may choose not to participate.

8.3.2.1 Recruitment and Informed Consent

A maximum of 12 APPs will be recruited from each ED at the two study sites. Advanced Practice Providers (APPs) working in the Emergency Department for at least 6 months will be approached to determine interest in participation in this study. Those who are interested will provide written consent for study procedures.

A total of 300 participants will be recruited from the ED at the two study sites, Children's Hospital of Philadelphia and Children's Mercy Hospital in Kansas City. Potentially-eligible patients will be identified by APP subjects during the course of normal clinical care, if the APP subject is part of the patient's care team. If a patient is eligible based on information from clinical care, the APP subject will contact a research assistant. Research assistants will verify with the clinical team that patients meet all eligibility criteria and whether the patient has the capacity to consent for themselves. If a patient meets all inclusion / exclusion criteria, consent / HIPAA authorization will be obtained. Subjects who are 18 years old will provide written consent and HIPAA authorization for their own participation. Subjects who are 16 or 17 years old who are seen in the ED without a parent/legal guardian will provide written consent and HIPAA authorization for their own participation. Subjects who are 16 or 17 years old who are seen in the ED with a parent/legal guardian may elect to have their parent/legal guardian involved in the consent process if desired. In this scenario, subjects will provide assent and permission and HIPAA authorization will be obtained from the parent/legal guardian that is present. The consent for the study will encompass the contraceptive counseling with an option for completion of the subgroup interview. All participants will be given the opportunity to ask questions and decline participation. Completed consent documentation will be signed and dated by the designated study staff, and a copy will be provided to the participant. As required in 45 CFR 46.116, when a minor participant reaches the age of 18, and is still undergoing research procedures, fully informed re-consent will be conducted. Original consent forms will be stored electronically, in the REDCap Database, only accessible by Dr. Mollen and designated study staff. Participants will be reminded at all study appointments that participation is completely voluntary.

8.3.2.2 Protections against Risk

Participants will be informed that their participation in all aspects of the proposed study is entirely voluntary, and that they are free to withdraw at any time. Strict measures will be taken to ensure participant privacy and confidentiality. All data will be coded and then stored in the secure REDCap database, and all participants will be assigned a unique identification number. The master list linking identification numbers to identifying information will be stored separately from the study database. All personally identifiable information will be kept strictly confidential and stored in an encrypted document, on a dedicated research server only accessible by Dr. Mollen and the designated study staff. Original, signed and dated consent forms will be in password protected folders within

REDCap only accessible by Dr. Mollen and the designated study staff. Contact information for Dr. Mollen and the study team will be included on consent forms to allow participants to ask questions or raise concerns about the study. Should any specific concerns arise, the study team would intervene to address problems including, if needed, a change or discontinuation of study procedures. The mentor team and site IRB's will be informed of any concerns, and the IRB and NIH will be informed of any adverse events.

8.3.3 Potential Benefits of Trial Participation

In the long term, the findings of this study could contribute to a reduction in unintended pregnancies among adolescents. It is also possible that the information obtained through this study will be used to create new guidelines for adolescent-centered contraceptive services, which could directly benefit the study population in the future. The minimal risks of participation are reasonable in relation to these generalizable benefits.

8.3.4 Risk-Benefit Assessment

As there is no more than minimal risk to study participation, and potential for minimal direct benefits and significant indirect benefits, we feel that the benefit outweighs the risk of participation.

8.4 Recruitment Strategy

APPs who have at least six months of experience will be recruited from each hospital's Emergency Department. Study team members will consent APPs if they are willing and interested in study procedures.

Potentially-eligible patients will be identified by APP subjects during the course of normal clinical care in the Emergency Department, if the APP subject is part of the patient's care team. Females ages 16-18 years old (inclusive) who present at the Emergency Department with any chief complaint, will be eligible. Adolescents will be excluded if they are too ill to be screened; have developmental delay limiting participation; present after sexual assault; or are pregnant, as per a pregnancy test conducted as part of standard clinical care. Through standard clinical care, APP subjects will also be able to determine those patients who are at high risk for pregnancy, defined as those who: report recent (within last 6 months) or likely future sexual activity (within the next 3 months); do not desire pregnancy within the next year; are not using hormonal contraception or an intrauterine device; and are not currently pregnant.³⁸ After identifying a potentially eligible subject based on these criteria, APP subjects will contact Emergency Department Research Assistants (RA). Research assistants will verify with the clinical team that patients meet all eligibility criteria and whether the patient has the capacity to provide consent. Both study sites are staffed with RAs 16 hours/day who are trained to monitor the ED electronic track board for potential research subjects for ED-based studies. The RA will confirm eligibility with the clinical care team. If a patient meets all inclusion / exclusion criteria, written consent / HIPAA authorization will be obtained. Subjects who are 18 years old will provide written consent and HIPAA authorization for their own participation. Subjects who are 16 or 17 years old who are seen in the ED without a parent/legal guardian will provide written consent and HIPAA authorization for their own participation. Subjects who are 16 or 17 years old who are seen

in the ED with a parent/legal guardian may elect to have their parent/legal guardian involved in the consent process if desired. In this scenario, subjects will provide assent and permission and HIPAA authorization will be obtained from the parent/legal guardian that is present.

8.5 Informed Consent/Assent and HIPAA Authorization

If eligible, a study team member will obtain APPs informed consent for study procedures.

If eligible, a study team member will obtain patient's informed consent for the study procedures. HIPAA Authorization will be obtained as part of the consent procedures. Study team members will verify with the clinical care team that the patient has the capacity to consent. Subjects who are 18 years old will provide written consent and HIPAA authorization for their own participation. Subjects who are 16 or 17 years old who are seen in the ED without a parent/legal guardian will provide written consent and HIPAA authorization for their own participation. Subjects who are 16 or 17 years old who are seen in the ED with a parent/legal guardian may elect to have their parent/legal guardian involved in the consent process if desired. In this scenario, subjects will provide assent and permission and HIPAA authorization will be obtained from the parent/legal guardian that is present. **Payment to Subjects/Families**

8.5.1 Reimbursement for travel, parking and meals

APPs will receive no reimbursements. Training will be provided free of cost.

For those participants attending in-person follow-up interviews, reimbursement for SEPTA tokens or CHOP parking vouchers will be provided (as appropriate).

8.5.2 Payments to subject for time, effort and inconvenience (i.e. compensation)

APPs will receive no payment for participation.

Patients will receive remuneration for each completed study assessment according to the following schedule:

- Contraceptive counseling and feedback questionnaire: \$20 to participant
- Post-counseling interview: \$20 to participant

9 PUBLICATION

Data from the study will be submitted for abstract presentation and publication.

10 REFERENCES

1. Hoffman SD, Maynard RA. *Kids having kids: Economic costs & social consequences of teen pregnancy*. The Urban Institute; 2008.
 2. Teen Childbearing Cost Taxpayers \$9.4 Billion in 2010 [press release]. 2013.
 3. Miller E, Goldstein S, McCauley HL, Jones KA, Dick RN, Jetton J, et al. A School-health center intervention for abusive adolescent relationships: A cluster RCT. *Pediatrics* 2015; 135(1): 76-85.
 4. Guttmacher Institute. Adolescent pregnancy and its outcomes across countries. Fact
-

- Sheet; August 2015. <https://www.guttmacher.org/fact-sheet/adolescent-pregnancy-and-its-outcomes-across-countries>; accessed January 12, 2018.
5. Lindberg L, Santelli J, Desai S. Understanding the decline in adolescent fertility in the United States, 2007-2012. *J Adol Health* 2016; 59(5):577-583.
 6. Santelli J, Lindberg L, Finer L, Singh S. Explaining recent declines in adolescent pregnancy in the United States: the contribution of abstinence and improved contraceptive use. *Am J Public Health* 2007;97:150-156.
 7. Sonfield A, Hasstedt K, Gold RB. Moving Forward: Family Planning in the Era of Health Reform, New York: Guttmacher Institute, 2014. <https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform>; accessed March 1, 2018.
 8. Frost JJ, Darroch JE, Remez L. Improving contraceptive use in the United States. *In Brief*. Vol 1. New York: Guttmacher Institute; 2008.
 9. Santelli JS, Morrow B, Anderson JE, Lindberg LD. Contraceptive use and pregnancy risk among U.S. high school students, 1991–2003. *Perspect Sex Reprod Health*. 2006;38:106-111.
 10. Fine L, Mollen CJ: A pilot study to assess candidacy for emergency contraception and interest in sexual health education in a pediatric emergency department population *Pediatr Emerg Care* 2010; 26(6): 413-6.
 11. Ziv A, Boulet JR, Slap GB. Emergency department utilization by US adolescents. *Pediatrics* 1998;101:987-994.
 12. Chernick L, Kharbanda EO, Santelli J, Dyan P. Identifying adolescents at high risk of pregnancy in a pediatric emergency department. *J Adol Health* 2012; 51:171-178.
 13. Miller MK, Pickett ML, Leisner KL, Humiston SG. Sexual health behaviors, preferences for care, and use of health services among adolescents in pediatric emergency departments. *Ped Emerg Care*. 2013;29(8):907-11.
 14. Walton MA, Resko S, Whiteside L, Chermack ST, Zimmerman M, Cunningham RM. Sexual risk behaviors among teens at an urban emergency department: relationship with violent behaviors and substance use. *J Adolesc Health*. 2011;48(3):303-5.
 15. Jaccard J, Levitz N. Counseling adolescents about contraception: towards the development of an evidence-based protocol for contraceptive counselors. *J Adolesc Health*. 2013;52(4 Suppl):S6-13.
 16. Zuckerman B, Nathan S, Mate K. Preventing unintended pregnancy: a pediatric opportunity. *Pediatrics*. 2014 Feb;133(2):181-3.
 17. Gordon JA, Billings J, Asplin BR, Rhodes KV. Safety net research in emergency medicine proceedings of the Academic Emergency Medicine Consensus Conference on “The Unraveling Safety Net”. *Acad Emerg Med*. 2001;8(11):1024-9.
 18. Bernstein SL, D'Onofrio G. Public health in the emergency department: Academic Emergency Medicine consensus conference executive summary. *Acad Emerg Med*. 2009 Nov;16(11):1037-9.
 19. Hallfors DD, Iritani BJ, Miller WC, Bauer DJ. Sexual and drug behavior patterns and HIV and STD racial disparities: the need for new directions. *Am J Public Health* 2007;97(1):126-132.
 20. Miller MK, Randell KA, Barral R, Sherman AK, Miller E. Factors associated with interest in same-day contraception initiation among females in the pediatric emergency department. *J Adol Health* 2016; 58:154-59.
-

21. Miller MK, Champassak S, Goggin K, Kelly P, Dowd MD, Mollen CJ, et al. A brief intervention to reduce adolescent sexual risk behaviors: feasibility and impact. *J Adolescent Health*. 2014;54(2S):S11.
 22. Mollen CJ, Miller MK, Hayes KL, Barg FK. Developing emergency department-based education about emergency contraception: adolescent preferences. *Acad Emerg Med*. 2013;20(11):1164-70.
 23. Miller MK, Dowd MD, Hornberger L, Sherman AK. Acceptability of sexual health discussion and testing in the pediatric acute care setting. *Pediatr Emerg Care*. 2013;29(5):592-7.
 24. Chernick LS, Westhoff C, Ray M, Garcia M, Garth J, Santelli J, et al. Enhancing referral of sexually active adolescent females from the emergency department to family planning. *J Women's Health* 2015; 24(4):324-328.
 25. Mehta SD, Hall J, Lyss SB, Skolnik PR, Pealer LN, Kharasch S. Adult and pediatric emergency department sexually transmitted disease and HIV screening: programmatic overview and outcomes. *Acad Emerg Med*. 2007;14(3):250-258.
 26. Silva A, Glick NR, Lyss SB, Hutchinson AB, Gift TL, Pealer LN, Broussard D, Whitman S. Implementing an HIV and sexually transmitted disease screening program in an emergency department. *Ann Emerg Med*. 2007;49(5):564-72.
 27. Trent M, Chung SE, Burke M, Walker A, Ellen JM. Results of a randomized controlled trial of a brief behavioral intervention for pelvic inflammatory disease in adolescents. *J Pediatr Adolesc Gynecol*. 2010;23(2):96-101.
 28. Suffoletto B, Akers A, McGinnis KA, Calabria J, Wiesenfeld HC, Clark DB. A sex risk reduction text-message program for young adult females discharged from the emergency department. *J Adolesc Health*. 2013;53(3):387-93.
 29. Calderon Y, Cowan E, Nickerson J, Mathew S, Fetting J, Rosenberg M, Brusalis C, Chou K, Leider J, Bauman L. Educational effectiveness of an HIV pretest video for adolescents: a randomized controlled trial. *Pediatrics*. 2011;127(5):911-6.
 30. Mollen CJ, Miller MK, Hayes KL, Barg FK. Knowledge, attitudes, and beliefs about emergency contraception: a survey of female adolescents seeking care in the emergency department. *Ped Emerg Care*. 2013;29(4):469-74.
 31. Miller MK, Mollen CJ, O'Malley D, Owens R, Maliszewski GA, Goggin K, Kelly P. Providing adolescent sexual health care in the pediatric emergency department: views of health care providers. *Ped Emerg Care*. 2014;30(2):84-90.
 32. Miller MK, Plantz DM, Dowd MD, Mollen CJ, Reed J, Vaughn L, Gold MA. Pediatric emergency health care providers' knowledge, attitudes, and experiences regarding emergency contraception. *Acad Emerg Med*. 2011;18(6):605-12.
 33. Reed JL, Panches BE, Taylor RG, Macaluso M, Alessandrini EA, Kahn JA. A Qualitative analysis of adolescent and caregiver acceptability of universally offered gonorrhea and chlamydia screening in the pediatric emergency department. *Ann Emerg Med* 2017; 70(6):787-796.
 34. Goyal MK, Teach SJ, Badolato GM, Trent M, Chamberlain JM. Universal screening for sexually transmitted infections among asymptomatic adolescents in an urban emergency department: high acceptance but low prevalence of infections. *J Pediatr* 2016; 171:128-32.
 35. Chernick LS, Schnall R, Higgins T, Stockwell MS, Castano PM, Santelli J, et al. Barriers to and enablers of contraceptive use among adolescent females and their
-

- interest in an emergency department-based intervention. *Contraception* 2015; 91(3):217-225.
36. Mollen CJ, Lavelle JM, Hawkins LA, Ambrose C, Rudy BJ. Description of a novel emergency department-based HIV screening program for adolescents. *AIDS Patient Care and STDs* 2008; 22(6): 505-511.
 37. Cowan E, Leider J, Velastegui L, Wexler J, Velloza J, Calderon Y. A qualitative assessment of emergency department patients' knowledge, beliefs, attitudes and acceptance towards revised HIV testing strategies. *Acad Emerg Med* 2013; 20(3):287-294.
 38. Reed JL, Vaughn LM, Pomerantz WJ. Attitudes and knowledge regarding emergency contraception among emergency department adolescents and providers. *Pediatr Emerg Care* 2012; 28(8):775-9
 39. Office of Disease Prevention and Health Promotion. Healthy People 2020. <https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning/objectives>; Accessed December 12, 2017.
 40. National Institutes of Health. NICHD Research Priorities; <https://www.nichd.nih.gov/grants-contracts/research-areas/priorities>; Accessed January 4, 2018.
 41. National Center for Health Statistics. National Survey of Family Growth, 2013-2015. 2016; <https://www.cdc.gov/nchs/nsfg/>. Accessed January 15, 2018.
 42. Hoopes AJ, Benson SK, Howard HB, Morrison DM, Ko LK, Shafii T. Adolescent perspectives on patient-provider sexual health communication: a qualitative study. *J Prim Care Commun Health*. 2017; 8(4):332-337.
 43. Kumar MM. Long-acting reversible contraceptives for adolescents – more complex than “first-line.” *JAMA Peds*. 2018; 172(1):6-7.
 44. Ott MA, Sucato GS and the Committee on Adolescence. Contraception for adolescents. *Pediatrics*. 2014; 134(4):e1257-81.
 45. Madden T, Mullersman JL, Omvig KJ, Secura GM, Peipert JF. Structured contraceptive counseling provided by the Contraceptive CHOICE Project. *Contraception*. 2013; 88:243-249.
 46. Campol Haynes M, Ryan N, Saleh M, Winkel AF, Ades V. Contraceptive Knowledge Assessment: validity and reliability of a novel contraceptive Research tool. *Contraception* 2017; 95:190-197
 47. Oregon Health Authority. Oregon reproductive health program 2015 client satisfaction survey report. 2015; https://public.health.oregon.gov/HealthyPeopleFamilies/ReproductiveSexualHealth/Resources/Documents/County_Data_Sheets/2015_CSS_Statewide.pdf. Accessed January 12, 2017.
 48. Mollen CJ, Barg FK, Hayes KL, Gotcsik M, Blades NM, Schwarz D. Assessing attitudes about emergency contraception among urban, minority adolescent women: an in-depth interview study. *Pediatrics* 2008; 122(2):e395-e401.
 49. Guest G, Bunce A, Johnson L. How many interviews are enough?: An experiment with data saturation and variability. *Field Methods* 2006;18:59.
 50. Robin L, Dittus P, Whitaker D, Crosby R, Ethier K, Mezooff J, et al. Behavioral interventions to reduce incidence of HIV, STD, and pregnancy among adolescents: a decade in review. *J Adol Health* 2004;34(1):3-26.
-

51. Kraut-Becher J, Eisenberg M, Voytek C, Brown T, Metzger DS, Aral S. Examining racial disparities in HIV: lessons from sexually transmitted infections research. *JAIDS Journal of Acquired Immune Deficiency Syndromes* 2008;47:S20-S27.
 52. Jemmott JB 3rd, Jemmott LS, Fong GT. Abstinence and safer sex HIV risk-reduction interventions for African American adolescents: a randomized controlled trial. *JAMA* 1998;279(19):1529-36.
 53. Weeks K, Levy SR, Zhu C, et al. Impact of a school-based AIDS prevention program on young adolescents' self-efficacy skills. *Health Educ Res* 1995;10:329-344.
 54. Kirby DB, Laris BA, Roller LA. Sex and HIV education programs: their impact on sexual behaviors of young people throughout the world. *J Adol Health* 2007;40(3):206-17.
 55. DiClemente RJ, Salazar LF, Crosby RA. A review of STD/HIV preventive interventions for adolescents: sustaining effects using an ecological approach. *J Pediatr Psych* 2007;32.8:888-906
 56. Schwartländer B, Stover J, Hallett T, Atun R, Avila C, Gouws E, et al. Towards an improved investment approach for an effective response to HIV/AIDS. *The Lancet* 2011;377(9782):2031-2041.
 57. Levinson R, Wan CK, Beamer LJ. The contraceptive self-efficacy scale: analysis in four samples. *J Youth Adolesc.* 1998; 27(6):773-793.
-